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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,870	04/12/2001	Masad J. Damha	1770-206US FC	5859

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/25/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,870	Applicant(s) DAMHA ET AL.	
	Examiner Janet L. Epps-Ford, Ph.D.	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-6 and 18-20 in Paper No. 15 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 7-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 15.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6, and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18, and those claims dependent thereon, recite oligonucleotides "consisting essentially of" arabinose sugars. According to MPEP § 2111.03, the transitional phrase "'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." However, the scope of the claimed oligonucleotides, consisting essentially of arabinose sugars, is vague and indefinite since neither the claims nor the specification as filed

clearly define what other sugars may be included in the claimed oligonucleotides and not materially affect the basic and novel characteristics of the claimed oligonucleotides.

Claim 2 recites "[T]he composition of claim 1, wherein said oligonucleotide has the formula:" This phrase is vague and indefinite since it is unclear which oligonucleotide as recited in claim 1 Applicants are referring to. Claim 1 recites two oligonucleotides, an oligonucleotide consisting essentially of arabinose sugars hybridizing to a single stranded RNA to induce RNase H, and an oligonucleotide consisting essentially of arabinose sugars substituted at 2' position of the sugar ring with halogen, alkyl, alkylhalide, alkylsulfhydryl, allyl, amino, aryl, alkoxy, or azido.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 2 and 9 recite the broad recitation of a halogen, alkylhalide or alkylsulfhydryl, and the claim also recites fluorine, chlorine, bromine, iodine, -

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CH₂F and -SCH₃, which are narrower statements of the limitations halogen, alkylhalide or alkylsulfhydryl.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 4-6, and 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer, Jr. et al. (US Patent No. 5,177,196).

The instant claims are drawn to a composition to selectively prevent gene transcription and expression in a sequence specific manner; which comprises an effective amount of at least one selected from the group consisting of (1) an oligonucleotide consisting essentially of arabinose sugars, and (2) an oligonucleotide consisting essentially of arabinose sugars substituted at 2' position of the sugar ring with halogen, alkyl, alkylhalide, alkylsulfhydryl, allyl, amino, aryl, alkoxy, or azido and hybridizing to duplex DNA/DNA or DNA/RNA to form a triple helical complex, in associated with an acceptable carrier.

Since the scope of the instant claims are vague and indefinite, for the reasons set forth in the above rejection, prior art will be applied to the extent that it discloses compositions comprising oligonucleotides comprising at least one arabinose sugar.

Meyer, Jr. et al. disclose novel oligonucleotide compositions formed from α -D-arabinofuranosyl nucleoside monomers represented by formulas Ia-Ib, see col. 2, line 44 through col. 3, line 40. The oligonucleotides of Meyer, Jr. et al. are disclosed as being useful as

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chemotherapeutic agents to control the expression of gene sequences or to inhibit mRNA translation (col. 3, lines 66-68), these gene sequences may be unique to an invading organism, such as a virus, a fungus or a bacterium (col. 1, lines 28-31).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-6 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. (US Patent No. 5,646,126) in view of Chu et al. (US Patent No. 5,808,040) and Meyer, Jr. et al. (US Patent No. 5,177,196).

The instant claims are drawn to a composition to selectively prevent gene transcription and expression in a sequence specific manner; which comprises an effective amount of at least one selected from the group consisting of an oligonucleotide consisting essentially of arabinose sugars, and an oligonucleotide consisting essentially of arabinose sugars substituted at 2' position of the sugar ring with halogen, alkyl, alkylhalide, alkylsulfhydryl, allyl, amino, aryl, alkoxy, or azido.

Cheng et al. describe oligonucleotides comprising 2'-deoxy, 2'-fluoro or 2'-difluoro nucleosides, wherein between 8 and 18 of said nucleosides are linked consecutively, see Figure 1, formula 2, see also claim 1. Specifically, the compounds of Cheng et al. encompasses wherein the R1 and R2 substituents of the 2' position of the nucleosides comprises either H or F, or wherein both R1 and R2 are F (fluorine) see col. 63, lines 24-25. Additionally, Cheng et al.

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teach that ODNs (oligonucleotides) including α and β arabinosides, are included within the scope of the invention (col. 9, lines 33-39).

Cheng et al. does not specifically disclose isolated oligonucleotides comprising arabinose sugars and 2'-fluoro or 2'-difluoro modified nucleosides consecutively linked in the same molecule.

Chu et al. teach a method for stabilizing oligonucleotides by including 2'-deoxy-2'-fluoro-arabinofuranosyl nucleosides into the oligonucleotides (see abstract). Additionally, Chu et al. teach that 2'-deoxy-2'-fluoro- β -L arabinosyluridine is a potent antiviral agent against HBV and EBV (see col. 2, lines 38-51).

It would have been obvious to one of ordinary skill in the art at the time of filing to modify the oligonucleotides of Cheng et al. with the teachings of Chu et al. to produce the compositions of the present invention. It would have been obvious to modify the oligonucleotides of Cheng et al. to comprise 2'-difluoro or 2'-fluoro arabinosyl nucleosides because, Cheng et al. expressly teach that their disclosed invention encompasses oligonucleotides comprising or including α and β arabinosides. Moreover, one of ordinary skill in the art seeking to enhance the properties of an oligonucleotide would have been motivated to modify the teachings of Cheng et al. to design the compounds of the present invention because Chu et al. teach that oligonucleotide stability can be increased by introducing 2'-deoxy-2'-fluoro-arabinofuranosyl nucleosides into the oligonucleotide structure. Additionally, Chu et al. teach that 2'-deoxy-2'-fluoro-arabinofuranosyl nucleosides possess potent antiviral properties. One of ordinary skill in the art would have had a reasonable expectation of success in designing the compounds according to the present invention, since Chu et al. describes the synthetic steps

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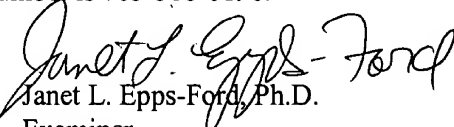
necessary for introducing 2'-deoxy-2'-fluoro-arabinofuranosyl moieties into an oligonucleotide structure.

Therefore, the invention as a whole would have been *prima facie* obvious over Cheng et al. in view of Chu et al.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on Monday-Thursday, 8:30 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Janet L. Epps-Ford, Ph.D.
Examiner
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JLE